

LISTING OF CLAIMS:

This listing of claims will replace all prior versions and listing of claims in the application. The following amendments are without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed.

1. (Previously presented) A method of treating or reducing the risk of developing a depressive disorder in a subject in need thereof, comprising the steps of:

(a) providing a pharmaceutical composition comprising:

- (i) about 1% testosterone;
- (ii) about 0.1% to about 5% isopropyl myristate;
- (iii) about 0.1% to about 5% thickening agent;
- (iv) about 45% to about 90% lower alcohol; and
- (v) water in an amount sufficient to total 100%

wherein the percentages are on a weight-to-weight basis of the composition; and

(b) administering a therapeutically effective amount of the composition to an area of skin of the subject in a single daily dose sufficient for delivery of the testosterone to the blood stream of the subject,

wherein the serum testosterone concentration is substantially maintained between about 400 ng testosterone per dL to about 1050 ng testosterone per dL.

2. (Canceled)

3. (Canceled)

4. (Canceled)

5. (Canceled)

6. (Previously presented) The method of claim 1, wherein the thickening agent comprises about 0.1% to about 5% polyacrylic acid.

7. (Original) The method of claim 6, wherein the thickening agent comprises about 0.9 % polyacrylic acid.

8. (Previously presented) The method of claim 6, wherein the polyacrylic acid is carboxypolymethylene.

9. (Previously presented) The method of claim 1, wherein the lower alcohol comprises about 72.5% ethanol or isopropanol.

10. (Canceled)

11. (Previously presented) The method of claim 1, wherein the composition weighs equal to or less than about 100 grams.

12. (Previously presented) The method of claim 1, wherein the composition weighs about 1.0 grams to about 10 grams.

13. (Previously presented) The method of claim 1, wherein the composition weighs about 2.5 grams to about 7.5 grams.

14. (Previously presented) The method of claim 1, wherein the composition weighs about 5.0 grams.

15. (Previously presented) The method of claim 1, wherein the composition is capable of releasing the testosterone after applying the composition to the skin at a rate and duration that achieves circulating serum concentration of the testosterone greater than about 400 ng testosterone per dl serum during a time period beginning about 2 hours after administration and ending about 24 hours after administration.

16. (Canceled)

17. (Previously presented) The method of claim 1, wherein for each about 0.1 gram per day application of the composition to the skin, an increase of at least about 5 ng/dl in serum testosterone concentration results in the subject.

18. (Previously presented) The method of claim 1, wherein the composition is provided to the subject for daily administration in about a 0.1 g to about a 10g dose.

19. (Canceled)

20. (Canceled)

21. (Canceled)

22. (Previously presented) The method of claim 1, wherein the composition is provided to the subject in one or more packets.

23. (Original) The method of claim 22, wherein the packet comprises a polyethylene liner between the composition and inner surface of the packet.

24. (Previously presented) The method of claim 1, wherein the composition is provided as a separate component to a kit.

25. (Previously presented) The method of claim 1, wherein the subject has a pretreatment serum testosterone concentration less than about 300 ng/dl.

26. (Original) The method of claim 25, wherein after at least about 30 days of daily administration serum testosterone concentration in the subject is at least about 490 ng/dl to about 860 ng/dl.

27. (Original) The method of claim 25, wherein after at least about 30 days of daily administration total serum androgen concentration in the subject is greater than about 372 ng/dl.

28. (Previously presented) The method of claim 1, wherein the composition is administered for at least about 7 days.

29. (Canceled)

30. (Canceled)

31. (Canceled)

- 32. (Canceled)
- 33. (Canceled)
- 34. (Canceled)
- 35. (Canceled)
- 36. (Canceled)
- 37. (Canceled)
- 38. (Canceled)
- 39. (Canceled)
- 40. (Canceled)
- 41. (Canceled)
- 42. (Canceled)
- 43. (Previously presented) A method of transdermally delivering testosterone to a male subject in need thereof, comprising the steps of:
 - a. providing a hydroalcoholic gel pharmaceutical composition, consisting essentially of:
 - i. about 1% testosterone;
 - ii. about 45% to about 90% (w/w) alcohol selected from the group consisting of ethanol (95% w/w) and isopropanol;
 - iii. isostearic acid;
 - iv. about 0.1% to about 5% (w/w) thickening agent; and
 - v. water; and
 - b. administering the composition to skin of the male subject wherein upon once daily administration of the composition, the testosterone is absorbed into bloodstream of the subject such that the circulating serum concentration of testosterone is greater than about 400 ng of testosterone

per dl serum during a time period beginning about 2 hours after administration and ending about 24 hours after administration.

44. (Previously presented) The method of claim 43, wherein the isostearic acid is present in an amount greater than about 0.1% weight to weight of the composition.

45. (Previously presented) The method of claim 43, wherein the isostearic acid is present in an amount of about 0.01% to about 50% weight to weight of the composition.

46. (Previously presented) The method of claim 43, wherein the composition consists essentially of:

- a. about 1% (w/w) testosterone;
- b. about 45% to about 90% (w/w) ethanol (95% w/w);
- c. about 0.1% to about 5% (w/w) isostearic acid;
- d. about 0.1% to about 5% (w/w) thickening agent; and
- e. water.

47. (Previously presented) The method of claim 43, wherein the thickening agent is comprises polyacrylic acid present in an amount of about 0.9% weight to weight of the composition.

48. (Previously presented) The method of claim 47, wherein the polyacrylic acid is carboxypolyethylene.

49. (Previously presented) The method of claim 46, wherein after applying the composition to the skin of the male subject, the testosterone is absorbed into the bloodstream of the subject in an amount of at least about 10µg per day.

50. (Previously presented) The method of claim 46, wherein the serum testosterone concentration is maintained between about 400 ng of testosterone per dl serum to about 1050 ng of testosterone per dl serum.

51. (Previously presented) The method of claim 46, wherein for each about 0.1 gram per day application of the composition to the skin, an increase of at least about 5 ng/dl in serum testosterone concentration results in the subject.

52. (Previously presented) The method of claim 46, wherein after at least about 30 days of daily administration serum testosterone concentration in the subject is at least about 490 ng/dl to about 860 ng/dl.

53. (Previously presented) The method of claim 46, wherein after at least about 30 days of daily administration total serum androgen concentration in the subject is greater than about 372 ng/dl.